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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,143	07/25/2002	Brian Algar	7678.576a.1	7688

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WORKMAN NYDEGGER
(F/K/A WORKMAN NYDEGGER & SEELEY)
60 EAST SOUTH TEMPLE
1000 EAGLE GATE TOWER
SALT LAKE CITY, UT 84111

EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,143	ALGAR, BRIAN	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/18/06 (election)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,35 and 37-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33,35 and 37-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/19/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Specification

Applicant is requested to amend the first line of the specification to refer to the claim for priority under Rule 371 to PCT/GB00/03141, filed 08/14/2000.

Drawings

1) Insofar as can be determined, no drawings are present in the examiner's electronic ("E-Dan") file. Figures should be submitted when responding to this Office action.

2) The heading "Brief Description of the Drawings" should be inserted in the specification at an appropriate point.

Information Disclosure Statement

The Information Disclosure Statement filed 07/19/05 fails to comply with 37 C.F.R. 1.98(a)(2), which requires a legible copy of each cited foreign patent document, non-patent literature publication, or relevant portion thereof. It has been placed in the application filed, but the foreign patent and non-patent literature references cited there have not been considered due to failure to enclose a legible copy of the reference(s).

Abstracts for SU 313794 and JP 01219038 were accessed by the examiner from the EPO website, since they were cited in the International Search report. For this reason, the examiner has placed his initial next to SU 313794 on the 1449 as being considered. Applicant will note that he has not done so next to JP 01 219038, however, because the 1449 indicates that an English language translation of same was submitted. That translation is not present in the examiner's electronic ("E-Dan") file, and was not available from the EPO website.

Election of Species Requirement

Upon further reconsideration in light of the facts of this case, the examiner hereby withdraws the previous election of species requirement.

Enablement Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33, 35 and 37-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make the inventive glasses.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth infra.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to bioactive glass compositions suitable for the treatment of dental caries. While the relative skill of those in the art is high (PHD or chemical engineer), this is outweighed by the unpredictable nature of the art.

Bioactive glasses for dental applications must be tailored to very narrow

specifications. These glasses function, at least in part, by remineralization which occurs through leaching of phosphorus and oxygen; specific oxides must be used to obtain the necessary solubility (SiO_2, CaO, Na_2O and P_2O_5, at a minimum): see the passage bridging co. 5, line 12 to col. 6, line 27 of USP 6,086,374. Similarly, the relative proportions of SiO_2, CaO and Na_2O must be carefully controlled to avoid producing insoluble products: see Fig. 5 of USP 5,891,233.

Thus , the prior art demonstrates that formulating bioactive glasses for dental applications is an empirical undertaking, since unpredictable variations in solubility are expected when using different oxides, or the same oxides in differing proportions.

2. The breadth of the claims

The claims are extremely broad, reciting bioactive glasses having only very generally characterized elemental compositions (overall percents of P, F and O, for example), but without specifying the particular oxides used, and their specific relative amounts.

3. The amount of direction or guidance provided and the presence or absence of working examples

Insofar as the examiner can determine based on the file before him, the specification provides no guidance whatsoever as to the particular oxides used and their

specific relative proportions, other than to briefly mention P_2O_5 (the basis for Applicant's election of species). No figures are present in the examiner's electronic ("E-Dan") file, so the particular glass compositions referenced there are not readily apparent, nor are the specific compositions used in the working examples readily determinable.

4. The quantity of experimentation necessary

The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the claimed invention would function as inferred and contemplated by the specification with a reasonable expectation of success. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Scope of Enablement Rejection

Claims 1-33, 35 and 37-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment" of dental caries, does not reasonably provide enablement for its "prevention". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth infra.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to compositions and method for treating dental caries. The relative skill of those in the art is that of a D.D.S. While this level of skill is relatively high, it is outweighed by the unpredictability of "preventing" dental caries. Even the layman, e.g. the ordinary consumer of oral care products, will readily recognize that dental caries cannot be "prevented", *i.e.*, completely eliminated; the best that can be hoped for is a minimization of its occurrence. No definitive long-term

"prevention" of the condition is realistically possible. In the real world in which patients live, subsequent exposure to cariogenic agents is unavoidable, necessitating repeated administration to minimize risk of recurrence.

2. The breadth of the claims

The claims are very broad insofar as they recite compositions and methods which "prevent" dental caries, as well as treat same.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification and working examples provide no direction or guidance for "preventing" dental caries. They disclose only what is already known, *i.e.*, its occurrence can be minimized through diligent oral care.

4. The quantity of experimentation necessary

Dental caries can only be minimized; it cannot be completely eliminated ("prevented"). In the short term, it is relieved by the application of an oral care product to the patient's teeth. In the long term, it can be protected against by repeated, chronic administration as part of an oral care/therapy regimen, but the risk of lapses can never

be completely "prevented". The instant specification provides no examples of or guidance for "preventing" dental caries, and so one would have to resort to extensive and undue experimentation to achieve same, if it is in fact possible at all. (Perhaps "elimination" could in theory be achieved under certainly strictly controlled laboratory conditions, but no such laboratory models or conditions are disclosed).

"Use" Claims

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1) Claims 1-17, 21 and 22 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

2) Claims 1-17, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-17, 21 and 22 provide for the use of glass compositions, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Provisional Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-33, 35 and 37-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25

of copending Application No. 10/276,218. This is a provisional obviousness-type double patenting rejection.

The conflicting claims are substantially the same in scope as those recited instantly, except that the former specify the use of bioactive glasses in the treatment of sensitive teeth, whereas the latter specify their use in the treatment of dental caries. Sine the two conditions are so closely interrelated in etiology and occurrence however, such that a person requiring treatment for dental caries would generally also require treatment for tooth sensitivity (and vice versa), the treatment of both simultaneously by a dentist would have been obvious on its face in a self-evident manner.

Prior Art Cited by International Authority

The prior art cited by the International Search authority has been considered. Although three of the references were given "X" designations initially (on the International Search Report), it is noted that Applicant's claims were ultimately found allowable over same. See specifically paragraph 3 of the International Preliminary Examination Report. (Copies are of record in the electronic file). The examiner concurs with the factual finding there, namely that documents D1-D3 (SU 313794, JP 01219038 and USP 4,285,730) do not anticipate the instant claims since they are drawn to optical glasses and thus would not disclose compositions suitable for treating dental caries. (At the very least, they would not employ the proper combinations of oxides required to

provide sufficient solubility to allow phosphate, fluoride and other ions to leach out in effective amounts; see the discussion in the "Enablement" section supra).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614